

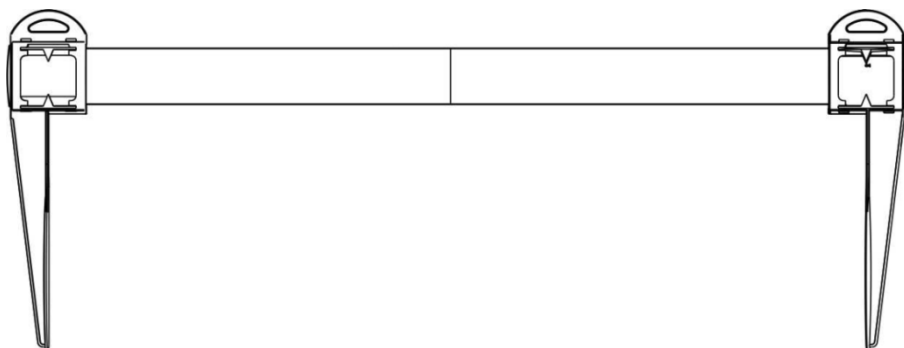


## Height Measurement

USER MANUAL

**HM80P**

Infant Height Stadiometer



Please keep the instruction manual at hand and follow instruction for use.

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## Explanation of Graphic Symbols on Label/Packaging

| Text/Symbol                                                                         | Meaning                                                                                                                                                     |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Caution. Failure to follow instructions may result in adverse events                                                                                        |
|    | Separate collection for waste of electrical and electronic equipment, in accordance with Directive 2002/96/EC. Do not dispose of device with everyday waste |
|    | Name and address of device manufacturer                                                                                                                     |
|    | Carefully read user manual before installation and usage, and follow instructions for use.                                                                  |
|    | Medical electrical device, Type B applied part                                                                                                              |
|    | Device catalogue number                                                                                                                                     |
|    | Name and address of authorized representative in the European Union (applicable for medical devices only)                                                   |
|    | Device is a medical device. Text indicates device category type                                                                                             |
|    | Manufacturer's batch or lot number for device                                                                                                               |
|   | Device's serial number                                                                                                                                      |
|  | Device's model number                                                                                                                                       |
|  | Device's Unique Device Identifier<br>(01) GTIN (11) Production date (21) Serial number                                                                      |
| e                                                                                   | Value in mass units. This is the difference between two consecutive display values, used to classify and verify a scale                                     |
|   | Device conforms to (EU) 2017/745 Regulation on Medical Devices. Four digit number is identifier for medical device Notified Body                            |
|  | Device claims conformity with essential regulations set by the relevant European Union legislation                                                          |

|                                                                                   |                                                                                                                                                                              |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Name and address of entity importing device                                                                                                                                  |
|  | Name and address of entity responsible for translating Information For Use                                                                                                   |
| CON.                                                                              | Event counter recording how many times protected-mode parameter adjustments relating to metrology-related characteristics (ex: gravity value) have been conducted for device |
|  | Device has received Taiwan NCC approval                                                                                                                                      |
|  | Device conforms to U.S. Federal Communications Commission regulations                                                                                                        |
|  | Device complies with all UK applicable product legislation                                                                                                                   |
|   | Device's polarity of power                                                                                                                                                   |

**In case of differences, icon on device itself takes precedence.**

**Copyright Notice**

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Charder Electronic Co., Ltd.  
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## I. Safety Notes

### **General Information**

Thank you for choosing this Charder Medical device. It is designed to be easy and straightforward to operate, but if you encounter any problems not addressed in this manual, please contact your local Charder service partner.

Before beginning operation of the device, please read this user manual carefully, and keep it in a safe place for reference. It contains important instructions regarding installation, proper usage, and maintenance.

### **Intended Purpose**

This medical device is designed to be used in accordance with national regulations, to measure height within specifications, for height-related usage by professionals.

### **Clinical Benefit**

Measurement results can be used by professionals to diagnose (and monitor) height-related issues.

### **Intended medical indications/contraindications**

Measurement: subject's body height.

### **Intended patient profile**

- (a) Age: no restrictions
- (b) Weight: no restrictions
- (c) Patient Conditions: require measurement of body height. Can physically fit within device capacity limits and be able to stand straight (non-infant versions only).

## **Intended user profile**

- (a) At least 20 years old
- (b) Minimum knowledge:
  - To be able to read at a high-school level and understand Arabic numerals (e.g. 1, 2, 3, 4...)
  - Basic hygiene knowledge
  - Trained in device's operation
  - Read the instruction manual
- (c) Language
  - Able to read the language of instruction manual and on-screen instructions
- (d) Qualifications
  - No special certifications or qualifications required

## **Residual Risk Evaluation**

- (a) All foreseeable risks have been evaluated and considered acceptable. Generally speaking, the most likely risk caused by incorrect usage of the device is less accurate measurement (or inability to use device to acquire measurement), which does not pose imminent physical risk to patient or user.
- (b) Benefit-risk ratio is considered acceptable. Height measurement meters are an important option for measuring patients. Usage of device is unlikely to result in harm to user or patient.

## **General Handling**

- Ensure all parts are properly locked and tightened before operating the device.
- Measurement accuracy requires the subject's feet, back, and head to be straightly aligned. Please note that height can vary throughout the day
- **CAUTION:** Do not use next to equipment that may cause electromagnetic or other types of interference.

## **Safety Instructions**

Before putting device into use, please read this user manual carefully. It contains important instructions for installation, usage, and maintenance of device.

The manufacturer shall not be liable for damages caused by failure to heed the following instructions:

- The device has an expected service life of 5 years when correctly handled, serviced, and periodically inspected in accordance with manufacturer's instructions.
- Improper installation will render the warranty null and void.
- Observe permissible ambient temperatures for use

## **Cleaning**

Device surface should be cleaned using alcohol-based wipes.

## **Maintenance**

Please contact your local Charder distributor for regular maintenance and calibration, regular checking of accuracy is recommended; frequency to be determined by level of use and state of device.

## **Warranty/Liability**

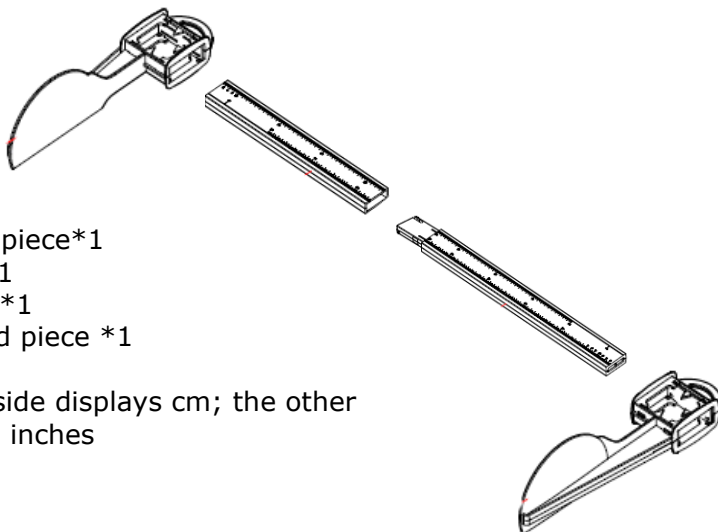
- The period of warranty shall be eighteen(18) months, beginning on the date of purchase. Please retain your receipt as proof of purchase.
- No responsibility shall be accepted for damage caused through any of the following reasons: unsuitable or improper storage or use, incorrect installation or commissioning by the owner or third parties, natural wear and tear, changes or modifications, incorrect or negligent handling, chemical, electrochemical, or electrical interference, unless damage is attributable to negligence on the part of Charder.
- This device does not contain any user-maintained parts. All maintenance, technical inspections, and repairs should be conducted by an authorized Charder service partner, using original Charder accessories and spare parts. Charder is not liable for any damages arising from improper maintenance or usage. Dismantlement of the device will void the warranty.

## **Incident Reporting**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer, EU representative (if device is used in EU member state), and competent authority of user/subject's member state.

## II. Installation

### A. Parts

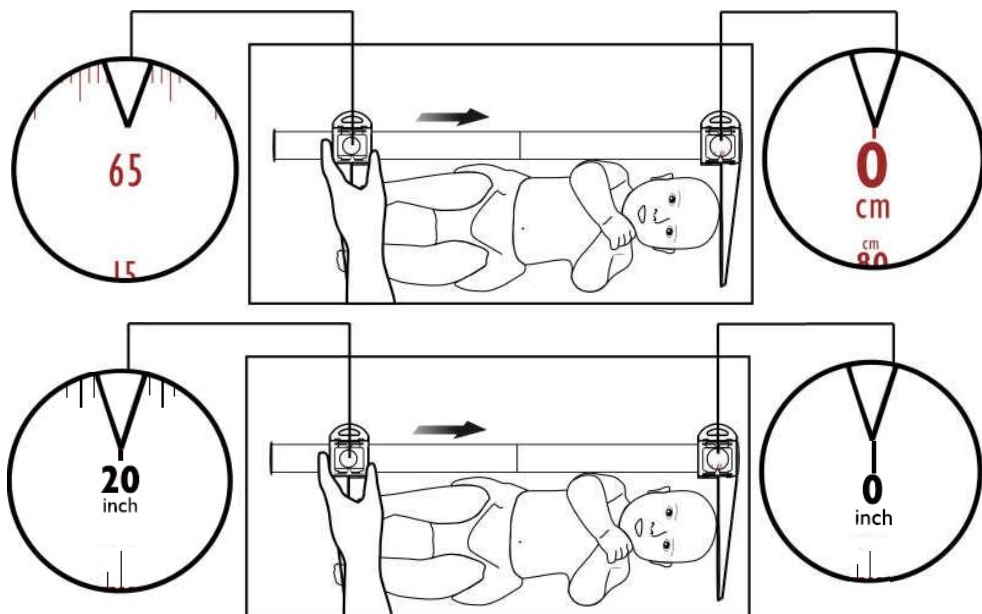


1. Left head piece\*1
2. Left rod \*1
3. Right rod \*1
4. Right head piece \*1

**NOTE:** one side displays cm; the other side displays inches

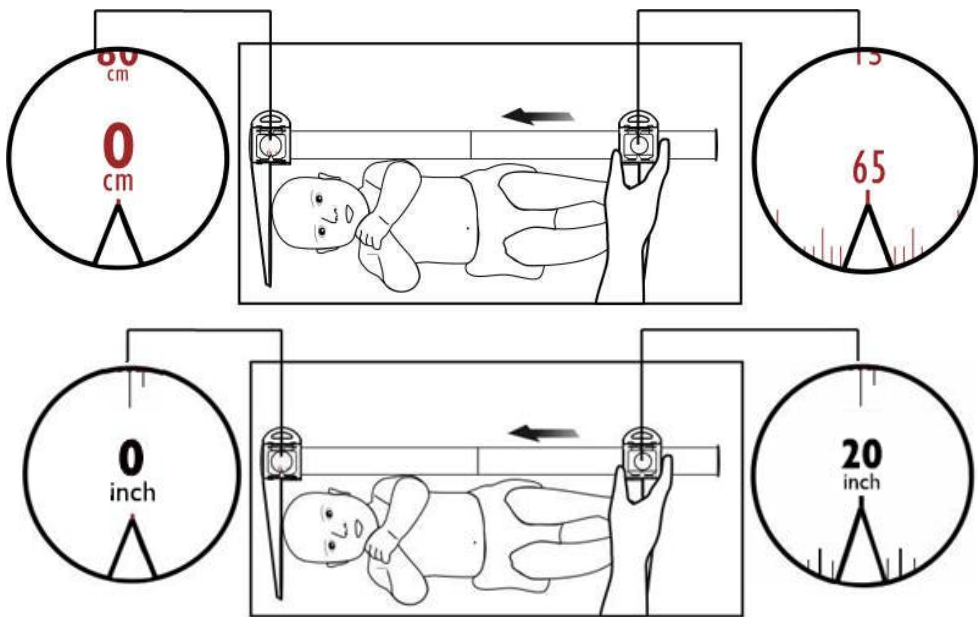
### III. Using Device

#### A. Left-handed usage



1. Fix right head piece at 0cm.
2. Straighten infant's feet.
3. Slide left head piece until it touches the soles of the infant's feet.
4. The reading on the left head piece is the length of the infant.

**B. Right-handed usage**



1. Fix left head piece at 0cm.
2. Straighten infant's feet.
3. Slide right head piece until it touches the soles of the infant's feet.
4. The reading on the right head piece is the length of the infant.

IV. Product Specifications

A. Device Information

| Model                 |               | HM80P                                                 |
|-----------------------|---------------|-------------------------------------------------------|
| Height Measurement    | Range         | 10-80 cm<br>3 15/16-31 1/2 in                         |
|                       | Graduation    | 1 mm<br>1/16 in                                       |
|                       | Accuracy      | ±10 mm                                                |
| Dimensions            | Overall       | 890(W) x 330(D) x 100(H) mm                           |
|                       | Device Weight | 0.7 kg                                                |
| Operation Environment |               | +5°C ~ +35°C<br>15% RH ~ 85% RH<br>700 hPa ~ 1060 hPa |
| Optional Accessories  |               | None                                                  |
| Standard Accessories  |               | User manual x1                                        |

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[illegible]

V. Declaration of Conformity

Manufacturer hereby declares that this product is in conformity with the regulations and standards outlined in the following directives:

|                                                                                        |                                                    |
|----------------------------------------------------------------------------------------|----------------------------------------------------|
|  2460 | <b>(EU) 2017/745 Regulation on Medical Devices</b> |
|----------------------------------------------------------------------------------------|----------------------------------------------------|

**RoHS Directive 2011/65/EU and Delegated Directive (EU) 2015/863**

(applicable if device is electronic device)

**Radio equipment and telecommunications terminal equipment Directive 2014/53/EU**

(applicable if device has wireless function)

**Part 15 of the Federal Communications Statement Rules**

This device may not cause harmful interference

This device must accept interference received without causing undesired operation

(Full Declaration of Conformity is available on manufacturer’s website)

**Authorized EU Representative:**

EU

REP

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**Manufactured by:**



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